

US EPA ARCHIVE DOCUMENT

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 05-01-86 OUT 10-30-86

Reviewed By Dennis G. Guse ^{WEC 10-31-86} Date 10-30-86

EPA Reg. No. or File Symbol 777-32

EPA Petition or EUP No. None

Date Division Received 04-15-86

Type Product General Disinfectant Spray

Data Accession No(s) 262593

Product Manager 31 (Lee)

Product Name Lysol Brand Disinfectant Basin/Tub/Tile Cleaner
(Aerosol)

Company Name Lehn & Fink Products

Submission Purpose Amendment for minor formula change (inerts),
two alternate formulations, and general label upgrading

Type Formulation Liquid pressurized aerosol spray

<u>Active Ingredient(s):</u>	<u>%</u>
Alkyl (67% C12, 25% C14, 7% C16, 1% C8, C10, C18) dimethyl benzyl ammonium chloride	0.08
Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride	0.02
Disinfectant use concentration (undiluted)	1000 ppm active quaternary

200.0 Introduction

200.1 Uses

The product is registered for general use (household) as an aerosol spray disinfectant on bathroom basins, tubs, tile, and other surfaces in and around the home (last accepted label dated 11-23-76). The accepted label bears claims for the product as a "one-step" disinfectant-cleaner, and for killing "strep" germs, influenza Type A2 virus, and athlete's foot fungi. The "one-step" claim pre-dates current efficacy data requirements in this regard (testing in the presence of 5% blood serum). Also, instead of a contact time, the accepted label states "After a few seconds, wipe off with clean cloth or sponge."

The current submission includes confirmatory efficacy data to support a minor formula change (inerts) with two alternate formulations, and a proposed revised label

200.2 Factors Affecting Review

Since the proposed amendment consists of updating and expansion (Herpes simplex Types 1 and 2 viruses) of efficacy claims and directions for use, in addition to confirmatory efficacy data to support a minor formula change and alternates, a complete review of previous and currently submitted efficacy data for this product, as well as the proposed labeling is called for in the light of current requirements.

200.3 Background

The inert ingredients in the currently proposed alternate formulas (received 04-15-86) differ only to a minor extent from the last accepted formula (received 03-17-82) for this product. Therefore, the confirmatory efficacy data (Accession No. 262593) submitted for the revised aerosol formulas may be utilized to support the minor formula changes, provided that the previously submitted basic and supplemental efficacy data meet the current requirements to support the basic aerosol formulation for this product as represented on the proposed, upgraded label.

In addition, the currently proposed alternate formula (received 04-15-86; designated V-0461-9) for this product is the same as the currently proposed formula (received 04-17-86) for Lysol Brand Disinfectant Basin/Tub/Tile Pump Spray Cleaner, EPA Reg. No. 777-51, except for the propellant. Although efficacy data developed on the aerosol formula may be utilized to support the non-aerosol pump spray formula (without propellant), data developed on the pump spray formula cannot be extrapolated to the aerosol formula, since the tests required for aerosol formulas are considered to be more stringent.

201.0 Data Summary

201.1 Previously Submitted Data

The following is a summary of previously submitted basic and supplemental efficacy data in support of the basic aerosol formulation under EPA Reg No. 777-32.

a. Brief Description of Tests

Efficacy data submitted for EPA Reg. No. 777-32, as follows:

Accession No.	240659	(received	05-05-67)
"	"	240649	(" 07-09-68)
"	"	240660	(" 07-15-69)
"	"	240647	(" 08-12-69)
"	"	004433	(" 05-03-71)
"	"	009052	(" 05-03-71)
"	"	240717	(" 11-15-71)
"	"	240716	(" 07-19-72)
"	"	240646	(" 06-05-75)

b. Test Summaries

Efficacy data developed by the AOAC Germicidal Spray Products Method is acceptable to support product effectiveness as an undiluted pressurized spray on pre-cleaned, hard, non-porous surfaces at 10 minutes contact time against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa (hospital/general disinfectant).

Efficacy data developed by the AOAC Germicidal Spray Products Method is acceptable to support effectiveness under the same conditions as a disinfectant against the additional bacterial pathogen Streptococcus pyogenes.

Efficacy data developed by the AOAC Germicidal Spray Products Method modified to conform to the basic elements of the AOAC Fungicidal Test is acceptable to support effectiveness under the same conditions as a fungicide (pathogenic) against Trichophyton interdigitale (now mentagrophytes).

Efficacy data developed by virucidal carrier spray test methods is acceptable to support effectiveness under the same conditions as a virucide against Influenza A2/Japan, Adenovirus Type 5, and Herpes simplex Type 1 viruses.

201.2 Currently Submitted Data

a. Brief Description of Tests

"Lysol Brand Disinfectant Basin, Tub, & Tile Formula V-0461-9 Germicidal Activity in the presence of Organic Soil - AOAC Germicidal Spray Test Confirmatory Data" & "Lysol Basin/Tub/Tile Cleaner Formula V-0451-9 Germicidal Activity in the Presence of Organic Soil - AOAC Germicidal Spray Test Confirmatory Data". Reports by Karen O'Donnell, Lehn & Fink Products Group, Montvale, NJ 07645, dated 02-10-86 & 04-10-86. (Accession No. 262593)

b. Test Summaries

1. The report cited above for Formula V-0461-9 is the same as that submitted for Lysol Brand Disinfectant Basin/Tub/Tile Pump Spray Cleaner, EPA Reg. No. 777-51, and was summarized in the review for that product

by TSS (Efficacy) dated 10-23-86.

2. The report cited above for Formula V-0451-9 is summarized as follows:

i. Method: AOAC Germicidal Spray Products Method.

ii. Modifications: 5% blood serum added to bacterial suspension.

iii. Samples: Lysol Basin/Tub/Tile Cleaner Formula V-0451-9 (Aerosol), EPA Reg. No. 777-32, Sample No. 1 (03-14-85; tested 03-27-85) and No. 2 (made 10-30-84; tested 03-27-85).

iv. Dilution: Undiluted spray.

v. Exposure: 10 minutes at room temperature.

vi. Test Organisms: Staphylococcus aureus (phenol res. 1:70, Salmonella choleraesuis (phenol res. 1:90), and Pseudomonas aeruginosa (phenol res. 1:90). The survival/slide on control carriers before and after drying in the presence of 5% blood serum was determined and was summarized in the review for EPA Reg. No. 777-51 by TSS (Efficacy) dated 10-23-86.

vii. Subculture Medium/Neutralizer: Lethen broth; checked for absence of stasis after inoculation and re-incubation of negative tubes with ca. 30-60 organisms/ml.

viii. Incubation: 48 hours at 37°C.

ix. Results:

<u>Test Organism</u>	<u>Test Sample</u>	<u>Positive/Total Carriers</u>
<u>Staphylococcus aureus</u>	1	0/30
"	2	0/30
<u>Salmonella choleraesuis</u>	1	0/30
"	2	0/30
<u>Pseudomonas aeruginosa</u>	1	0/30
"	2	0/30

3. Conclusions: The results for the currently proposed alternate formulas (designated V-0461-9 and V-0451-9) appear adequate to confirm efficacy for the minor formula change of the aerosol formula for this product. However, the previously submitted basic and supplemental efficacy data on file for this product do not support the claims as a "one-step" disinfectant-cleaner (in the presence of 5% blood serum) nor as a virucide against Herpes simplex Type 2 virus on the proposed, upgraded label.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 777-32

Date Division Received 04-15-86

Data Accession No(s). 262593

Product Manager No. 31 (Lee)

Product Name Lysol Brand Disinfectant Basin/Tub/Tile Cleaner (Aerosol)

Company Name Lehn & Fink Products

202.0 Recommendations

202.1 Efficacy Supported by the Data (Pre-Cleaned Surfaces)

- a. Previously Submitted Data (Accession Nos. 240659, 240649, 240660, 240647, 004433, 009052, 240717, 240716, and 240646)

The previously submitted basic and supplemental efficacy data developed by the AOAC Germicidal Spray Products Method are acceptable in meeting current requirements to support effectiveness of the original, aerosol, pressurized spray formulation for this product as a hospital/general disinfectant against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa, as a disinfectant against the additional bacterial pathogen Streptococcus faecalis, and as a fungicide (pathogenic) against Trichophyton interdigitale (now mentagrophytes) on pre-cleaned, hard, non-porous surfaces which are thoroughly wet by the spray for a contact time of 10 minutes.

The previously submitted supplemental efficacy data developed by virucidal carrier spray test methods are also acceptable in meeting current requirements to support effectiveness of the prototype product as a virucide against Influenza A2/Japan, Adenovirus Type 5, and Herpes simplex Type 1 viruses under the same conditions.

- b. Currently Submitted Data (Accession No. 262593)

Based on the above, the currently submitted confirmatory efficacy data developed by the AOAC Germicidal Spray Products Method are acceptable only to confirm effectiveness of the proposed alternate formulations for the minor formula change in the aerosol spray product on pre-cleaned, hard, non-porous surfaces which are thoroughly wet for a contact time of 10 minutes.

202.2 Efficacy Not Supported by the Data ("One-Step" & Herpes simplex Type 2)

The previously submitted basic and supplemental efficacy data on file for this product do not support the claim as a "one-step" disinfectant-cleaner (in the presence of 5% blood serum), nor the claim as a virucide against Herpes simplex Type 2 virus on the proposed label.

The currently submitted confirmatory efficacy data are not sufficient to support the claim as a "one-step" disinfectant-cleaner (in the presence of 5% blood serum).

202.3 Data Not Applicable to Support Efficacy (Liquid Pump Spray Formula)

Although data developed on a pressurized aerosol spray product, such as EPA Reg. No. 777-32, may be utilized to support efficacy of the same formula as a liquid pump spray (without propellant), such as EPA Reg. No. 777-51, the opposite is not true, since the tests performed with the aerosol product are considered to be more stringent. Therefore, the data developed on the liquid pump spray formula (without propellant) under EPA Reg. No. 777-51 cannot be utilized to support efficacy of this pressurized aerosol spray formula under EPA Reg. No. 777-32.

202.4 Additional Data Required to Support Efficacy ("One-Step" & Herpes simplex Type 2)

To support basic efficacy of the product for hospital/general use as a "one-step" disinfectant-cleaner in the presence of organic soil, data must be developed on the pressurized aerosol formula as indicated in the attached DIS/TSS-1 enclosure, item (c), modified to include 5% blood serum, according to the attached DIS/TSS-2 enclosure, item 4, with the reduced batch replication indicated in the DIS/TSS-2 enclosure, item 8 (2 samples representing 2 different batches, instead of 3). In addition, data must be submitted to show quantitative recovery (plate counts) of the test bacteria from untreated control carriers in the presence of 5% blood serum as indicated in the DIS/TSS-2 enclosure, item 6.

To support supplemental efficacy of the product as a disinfectant against additional bacterial pathogens, e.g., Streptococcus faecalis, in the presence of organic soil, data must be developed on the aerosol as indicated in the DIS/TSS-1 enclosure, item (d), modified to include 5% blood serum with reduced batch replication (1 sample instead of 2), and control carrier plate count data, as indicated above.

To support supplemental efficacy of the product as a fungicide (pathogenic) and virucide in the presence of organic soil, data must be developed on the aerosol as indicated in the attached DIS/TSS-6 enclosure, item (A), and DIS/TSS-7 enclosure, modified to include 5% blood serum with the reduced batch replication (1 sample instead of 2), as indicated above.

The currently submitted confirmatory efficacy data for the minor formula change in the aerosol spray product may be utilized in partial fulfillment of the above requirements.

203.0 Labeling

In lieu of additional data, delete all representations of this product as a "one-step" disinfectant-cleaner in the presence of organic soil. The directions for use must specify that all surfaces be pre-cleaned prior to disinfection.

In lieu of additional data, delete the claim for Herpes simplex Type 2 virus.

The label reference/illustration concerning toilet bowls must take into consideration the residual water in the bowl and its dilution effect. The following alternatives are suggested:

Delete the reference to or illustration of toilet bowls, or
Specify "toilet seats" or "exposed bowl surfaces"
~~removal or expulsion of residual bowl water prior to application~~
~~of the product as a disinfectant for toilet bowls.~~ WEC

The label must identify the major area(s) in which the product is recommended for use, e.g., homes, hotels, hospitals. 4-21-8